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Clinical Research Informatics

Thomas K. Houston
University of Massachusetts Medical School

Et al.

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QUERI
Quality Enhancement Research Initiative

University of Massachusetts Medical School
UMASS

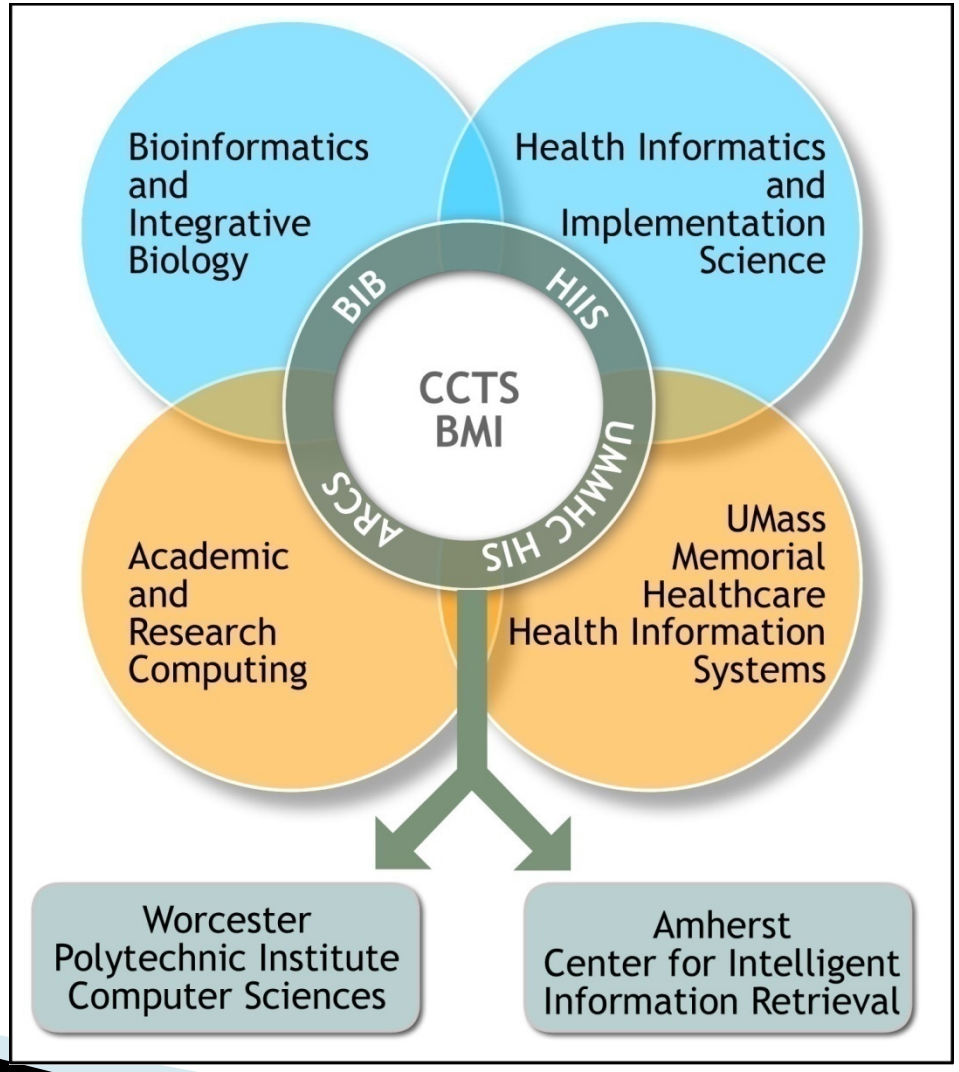
Clinical Research Informatics

Thomas Houston, MD, MPH

May 4, 2012

FINANCIAL DISCLOSURE:
Funding from NIH, AHRQ and VA
No industry funding
Unlabeled Use:
None to disclose

Informatics at UMMS/UMMHC



BRIDG

Biomedical Research Informatics Development Group

- Tom Houston, MD, MPH, Chief, Division of Health Informatics and Implementation Science, Quantitative Health Sciences
- Rajani Sadasivam, PhD
- Thomas English, PhD
- Ralph Zottola, PhD
- Timothy Hogan, PhD

Informatics

- Discipline focused on the acquisition, storage, and **optimal use** of information for health and healthcare

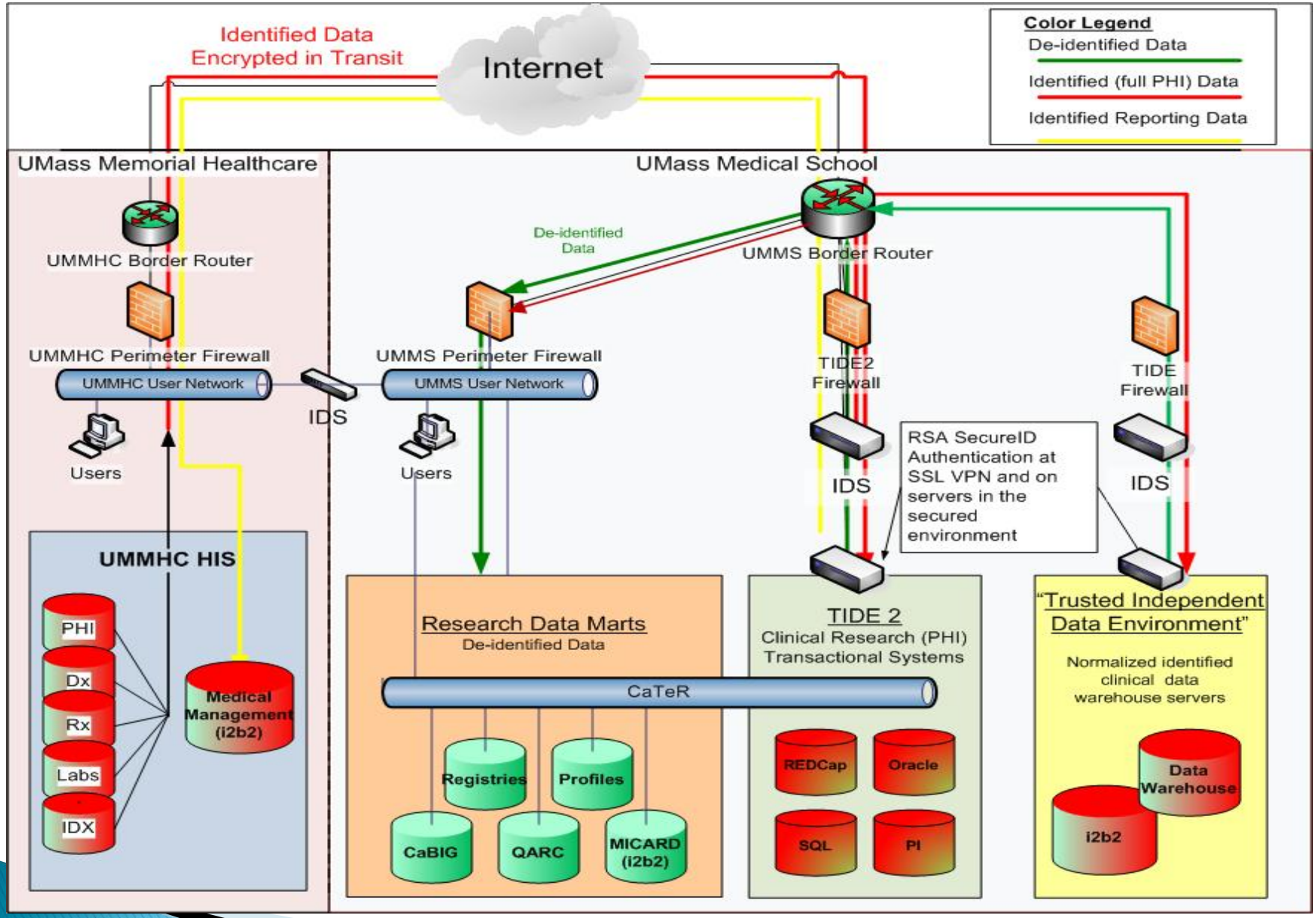
  - "Informatics is more about information than technology, with the latter being a tool, albeit an important one, to make best use of information."
    - Hersh BMC Medical Informatics 2009

Health IT

- HIT = the application of computers and technology in health care settings
  - Hersh BMC Medical Informatics 2009

Clinical research Informatics

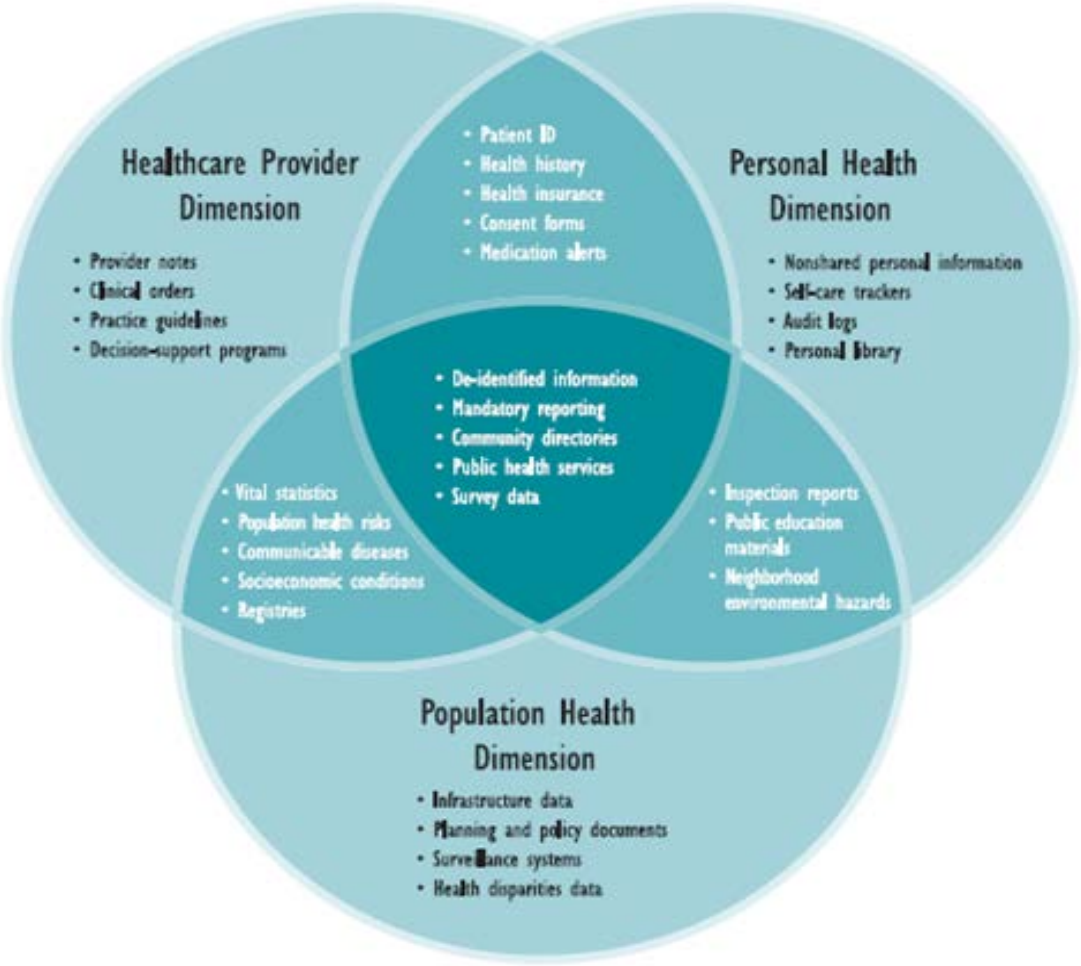
- “Development, application, and evaluation of theories, methods, and systems to optimize the design and conduct of clinical research and the analysis, interpretation, and dissemination of the information generated.”
  - Embi et al Clinical research informatics: challenges, opportunities and definition for an emerging domain. J Am Med Inform Assoc 2009


Identified Data
Encrypted in Transit
Internet
Color Legend
De-identified Data
Identified (full PHI) Data
Identified Reporting Data
UMass Memorial Healthcare
UMass Medical School
UMMHC Border Router
UMMS Border Router
De-identified
Data
UMMHC Perimeter Firewall
UMMS Perimeter Firewall
TIDE2
Firewall
TIDE
Firewall
UMMHC User Network
UMMS User Network
IDS
Users
Users
IDS
IDS
RSA SecureID
Authentication at
SSL VPN and on
servers in the
secured
environment
UMMHC HIS
PHI
Dx
Rx
Labs
IDX
Medical
Management
(i2b2)
Research Data Marts
De-identified Data
CaTeR
Registries
Profiles
CaBIG
QARC
MICARD
(i2b2)
TIDE 2
Clinical Research (PHI)
Transactional Systems
REDCap
Oracle
SQL
PI
"Trusted Independent
Data Environment"
Normalized identified
clinical data
warehouse servers
Data
Warehouse
i2b2

Development

- Usability Assessments
  - Expert-driven evaluation
  - User-driven evaluation
    - Quantitative (time on task)
    - Qualitative (cognitive think-aloud)
      - Jakob Nielson. Designing Web Usability: The Practice of Simplicity, 2000.

Personal Health Records (PHRs)

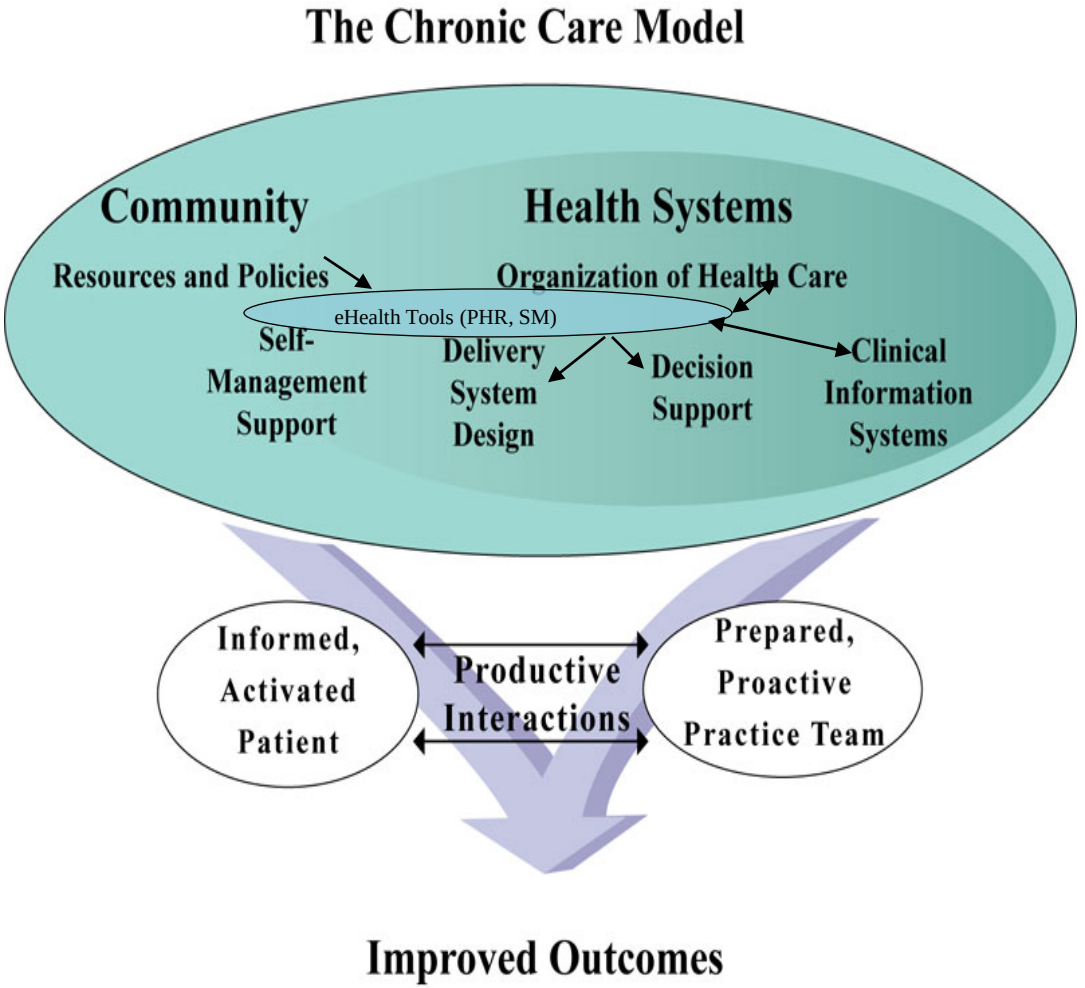


" A set of computer-based tools that allow people to access and coordinate their lifelong health information and make appropriate parts of it available to those who need it."

Markle Foundation, 2006

The Potential of PHRs:

- Enhanced Patient Satisfaction
- Patient Activation
- Enabled Self-Management
- Enhanced Communication
- Efficiency and Cost
- Quality and Safety



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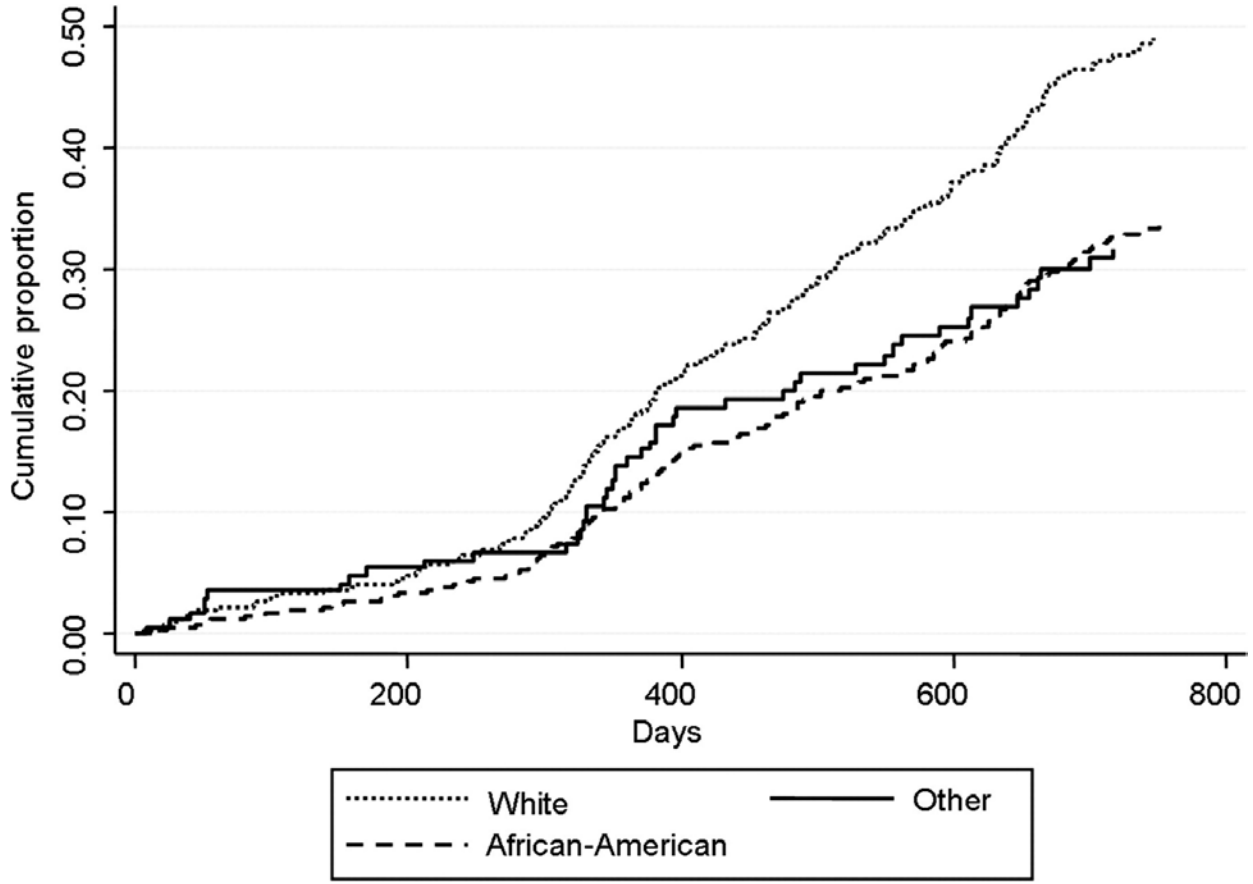
® ACP-ASIM Journals and Books

Disparities

Cumulative Proportion by Month of KPGA Enrollees Registered with KP.org from 10/1/05.



Roblin, Houston et al. JAMIA 2009;16:683-689

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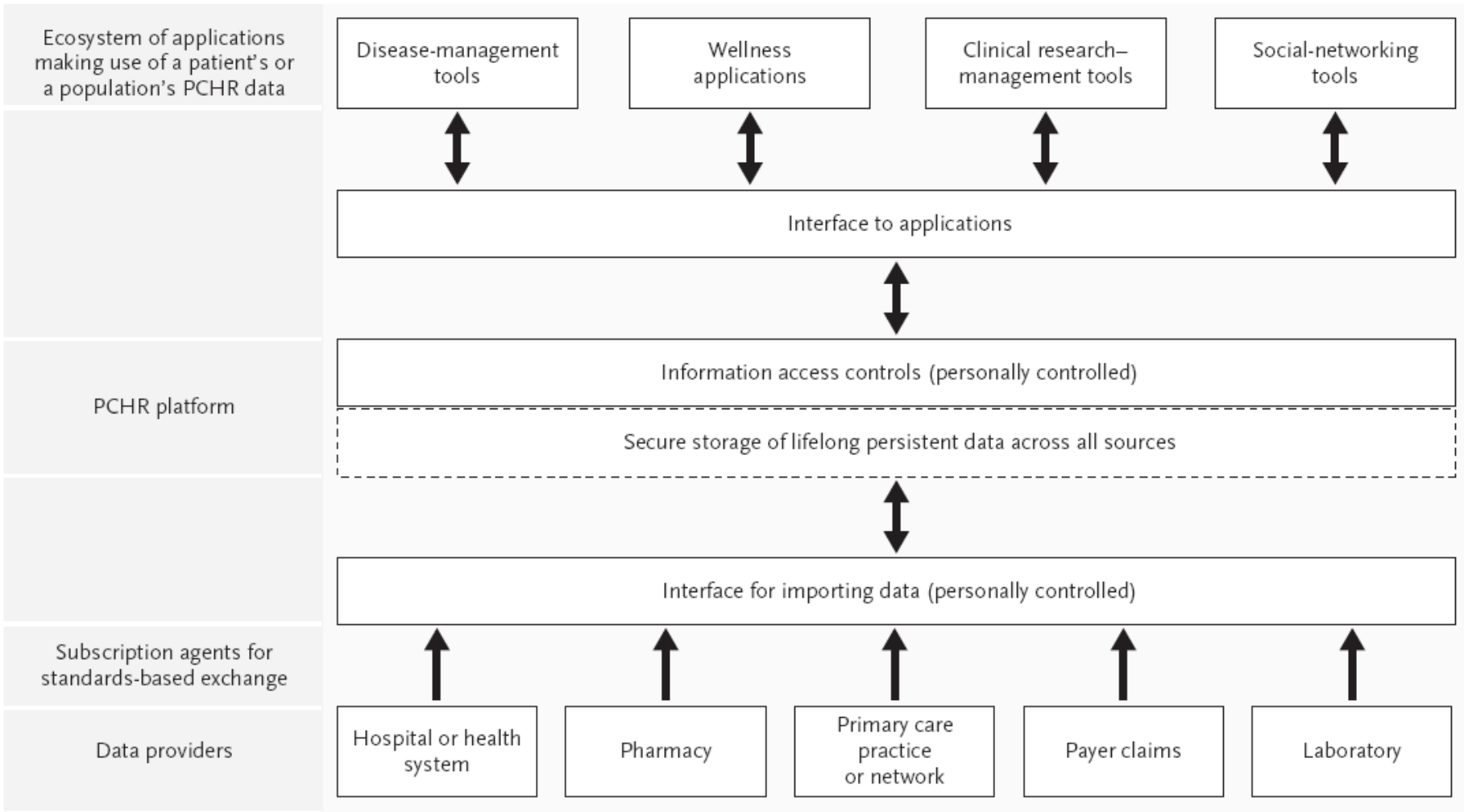
JAMIA



Mandl et al, NEJM 2008

LEVEL	FUNCTIONALITY
1	Collect patient information, such as self-reported demographic and risk factor information (health behaviors, symptoms, diagnoses, and medications)
2	Integrate patient information with clinical information through links to the electronic medical record and/or claims data
3	Interpret clinical information for the patient by translating clinical findings into lay language and delivering health information via a user-friendly interface
4	Provide individualized clinical recommendations to the patient, such as screening reminders, based on the patient's risk profile and on evidence-based guidelines
5	Facilitate informed patient action integrated with primary and specialty care through the provision of vetted health information resources, decision aids, risk calculators, personalized motivational messages, and logistical support for appointments and follow-up

Krist and Woolf, JAMA, 2011

eHealth QUERI

- Leadership
  - Tom Houston, MD, MPH (Director)
  - Bonnie Wakefield, PhD, RN, FAAN (Clinical Coordinator)
  - Timothy Hogan, PhD (Implementation Research Coordinator)
- Field Sites
  - Boston, Chicago, Salt Lake, Ann Arbor, Portland, Iowa City
- Data Center (West Haven VAMC)

eHealth QUERI Strategic Goals

1) To augment access and meaningful use of eHealth tools

2) To enhance veteran self-management and participation in collaborative care through the design, evaluation, and implementation of appropriate eHealth tools

Using Allscripts Data at UMass for Clinical Research

Thomas English PhD

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Department of Quantitative Health Sciences Division of Health Informatics and Implementation Science

University of Massachusetts Medical School

Center for Clinical and Translational Science

Quantitative Methods Core: Bruce Barton PhD

Biomedical Informatics Core: Tom Houston MD

4/20/2011

Purpose

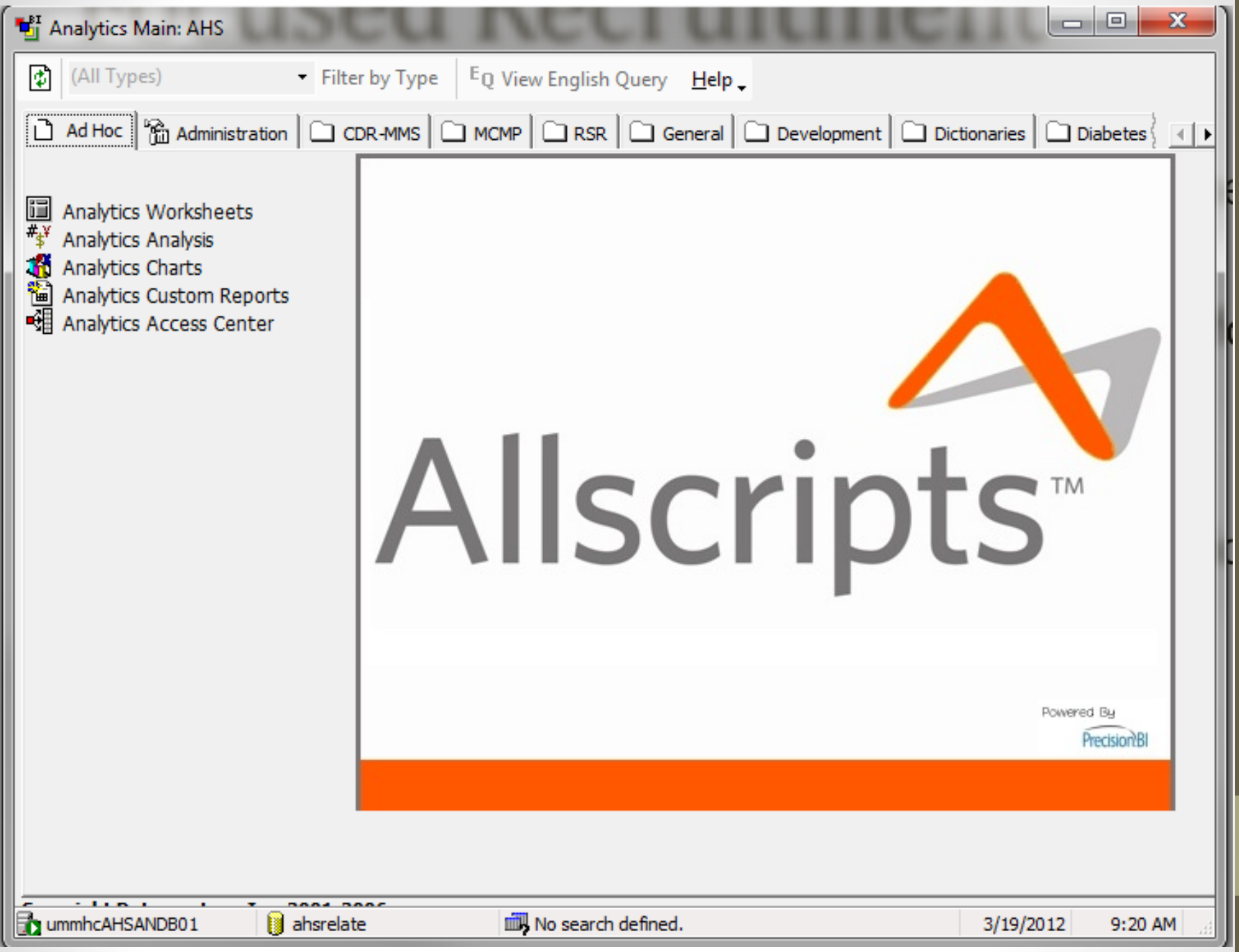
- Discuss the role Allscripts can play in your research
- Discuss how to access Allscripts data

Who am I?

- Health Informatics & Outcomes Researcher
- Former Allscripts Administrator
- Former Allscripts Analytics Administrator
- Design Studies
- Modify Systems
- Extract Data
- Analyze Data

How can Allscripts Help?

- Grant Preparation
- Cohort Discovery
- Data source
- Intervention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Administration
CDR-MMS
MCMP
RSR
General
Development
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Analytics Worksheets
Analytics Analysis
Analytics Charts
Analytics Custom Reports
Analytics Access Center
Allscripts™
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Grant Preparation

Grant Preparation

- Some data can be gathered prior to IRB approval
  - Power Calculations
  - Sample Size
  - Summary Statistics
- All research using Allscripts will be subject to IRB approval
- Individual data will not be gathered without prior IRB approval

Population Characteristics

- Race/Ethnicity
- Age
- Medications
- Lab results
- Immunizations
- Comorbidities

- Data about individuals will not be available until the IRB has approved the study.

Cohort Discovery

New England Newborn Screening Program

- How many children have:
  - SCID, DiGeorge Syndrome, Velo-Cardio-Facial Syndrome etc…
- Pulled cohorts from Micard and Allscripts
- Challenges:
  - ICD9 Codes
  - Matching Terminology

Focused Recruitment

- Suppose we did need to recruit the patients for the study. How would we?
- With Allscripts we can extract patient demographics including contact info. Mail, call, email…

Or

- Query the system to find out when potential participants will be at the clinic and approach them individually.

Data Source Example

Metformin & B12

- Resident research with no funding
- Can you pull the number of subjects we follow with diabetes who:

1. Are treated with metformin

2. Had a vitamin B12 level drawn within 2 years prior to starting metformin.

Metformin & B12

- Explore the effect of Metformin on Vitamin B12 levels
- Initial Plan: Find patients on Metformin that had a B12 level checked within 24 months prior to the start of Metformin.
- Contact the patients and repeat the Serum B12 if they are willing
- We found 1700 patients meeting the criteria

Metformin & B12

- 1700 Potential Participants
- But I did some digging.
- I found 600 of those patients had a serum B12 level after the start of Metformin already documented.
- We now have IRB approval to extract the data from Allscripts to conduct the analysis
- Now we can do the study using data already in the system as part of standard care. No recruiting! No Specimen Management!

B12 (6386 Results) Issues

- What do you do with non numeric values?
  - <50
  - >1500
- Average B12
  - 665.9
- What do the different codes mean?
  - hB12 n=3963 Average: 643
  - h**B12 n=2415 Average: 704

ED Visits

Emergency Department Visits

- Investigate trends and predictors of ED use
- Claims data
- Allscripts data
  - Problems
  - Medications
  - Hospitalizations
  - # Visits
  - Lab Results
  - Etc…..
- Data about physician and clinic characteristics
- Create predictive model to determine who is most likely to use the ED

ED Visit and No Other Care.

- N=25844
- Male:52% Female: 48%

Age Group	n	Percent
(<1)	457	1.77%
(1-10)	5584	21.61%
(11-19)	3584	13.87%
(20-39)	6668	25.80%
(40-64)	5965	23.08%
(65+)	3586	13.88%

ED Visit Race Data

Race	n	Percent
American Indian or Alaskan Native	12	0.05%
Asian	296	1.15%
Asian or pacific	5	0.02%
Black or African American	929	3.59%
Hispanic-	25	0.10%
Multi Racial	2	0.01%
Native Hawaiian or Other Pacific Islander	16	0.06%
Other Race	1805	6.98%
White	12749	49.33%
Unknown	10017	38.76%

ED Visit Count?

25844 Patients had 39265 ED Visits

Numbers represent the number of “Emergency Department “ document items in Allscripts.

May have duplicates and/or additional ED reports on the same visit.

# of Documents	% Population	% Visits
1	73.19%	48.17%
2	16.51%	21.73%
3	5.36%	10.59%
4	2.24%	5.91%
>=5	2.70%	13.60%

>5 shows 697 patients had 5340 ED reports

Allscripts as Part of an Intervention

AAFP Foundation Childhood Immunizations Project

- Goal: Improve Childhood Immunization Rates
- Intervention involved patient education, physician education, and tools enable by Allscripts.
- Used IDX, the scheduling system, to remind nurses to review immunizations on patients 19-35 months old.
- Used Allscripts to create lists of patients not up to date for physician to review and for us to contact in bulk using mailers
- Also gave quality scores to all physicians and benchmarked them against their peers

Childhood Immunizations

- Immunization rate increases significantly
- Largely due to finding missing documentation of Hep B vaccine given at the hospital
- 2010 AAFP Foundation Pfizer Immunization Best Practice Award

Closing the Feedback Loop

- AHRQ Grant
- Made Follow-up calls to patients presenting with acute illness
- Compared Human Calls vs. Automated Calls
- Analysis is under way
- Extracted data from Allscripts to gather participant contact info
- Added specific task types in Allscripts to inform physicians about their patients we called and how the patient was doing

Allscripts Diabetes

- Natural Experiment around Allscripts Implementation
- Investigated Diabetes Care Pre/Post Allscripts Implementation
- Analyzed data using Orders, Results, and Lab Values
- Allows us to find patients that have tests ordered but do not have them performed.

Allscripts Diabetes

- Post EHR Implementation patients were more likely to have an:
  - HbA1c<7
  - LDL<100
  - A Microalbumin Ordered

- **Data Collection 1 month vs. 4 hours**

Intervention Ideas

CKD Report Card generated in Allscripts Analytics will be part of an intervention.

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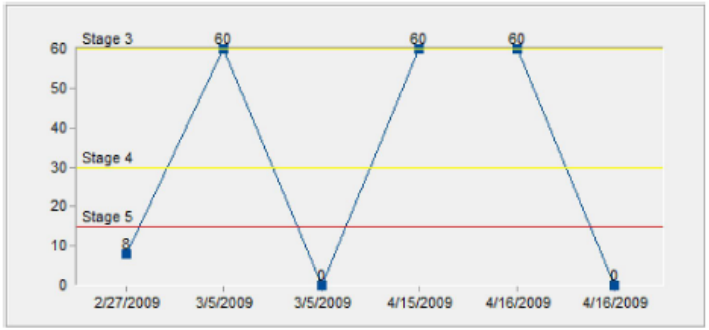
RENAL MEDICINE

CKD Report

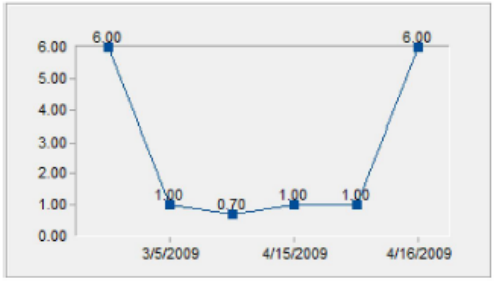
Patient Name: TEST, MARY PCP:
Patient MRN: 1506618

Glomerular Filtration Rate (GFR)



Stage 1 Kidney Damage Normal Function GFR>90
Stage 2 Kidney Damage Mild Funtion Decrease GFR 60-90
Stage 3 Kidney Damage Modrate Function Decrease GFR 60-30
Stage 4 Kidney Damage Severe Function Decrease GFR 15-30
Stage 5 Kidney Failure GFR<15

Creatinine



BP < 130/80

Diet Instructions

Limit dietary sodium to 2 g/24 hrs. Avoid salty snacks, canned soups, processed and fast food

Limit dietary potassium to 2 g/24 hrs. Limit tomatoes and tomato sauce, oranges and orange juice, bananas, potatoes (boiled potato is OK), avocadoes and cantaloupes.

Other Labs	Results	Date	Goal
Protein Urine			
MicroAlbumin	1	3/5/2009	
Calcium	9.0	4/16/2009	
Sodium Bicarbonate			>21
Phosphorus	2.6		
PTH			
Vitamin D	40	3/5/2009	>30
Potassium	5.0	4/17/2009	3.5-5.4
Serum Albumin	3.7		
Hemoglobin	14.0	11:34:00	>10
A1c	4.0	3/5/2009	<7%

Medications

ACE Inhibitor	Accupril 5 MG Oral Tablet
ARB	
Lipid Lowering	

Avoid Use of NSAID and other Nephrotoxic Medications

Recommended Referrals

Developed by UMass Medical School Quantitavitve Health Science Department and the CCTS and Umass Memorial Hospital Medical Management and Renal Medicine. Treatment Guidelines: http://www.kidney.org/professionals/kdoqi/guidelines_commentaries.cfm

Pragmatic Trial

- Grant Stipulates data must be a residual of usual care.
- Use Allscripts and patient portal to improve care
- Extract Allscripts data
  - Tasks
  - Documents
  - Orders
  - Patient reported outcomes
- Allscripts based tools
- Customize Allscripts workflows

Summary

Limitations

- Missing Data
- Noisy Data
- Linking Concepts to Data
- Confounding - by indication, by severity, etc Variations in data entry by provider and clinical setting
- Different Allscripts Functionality in UMass clinics

Strengths

- Real-world data
- Huge volumes of data
  - 622,254 Patients with an arrived visit since 1/1/2007
  - 2,396,711 Blood Pressures on 318418 patients
- Inexpensive to retrieve (relative to direct capture) Dually valuable for research and operations
- Access to grant opportunities calling for electronic data that is the residual of usual care

So, how does this work?

Services Available

- It is best to integrate Allscripts into your research from the beginning!!!
- Allscripts data and capabilities will affect:
  - Collect pilot data
  - Analysis of existing data
  - Study design
  - Intervention Design
  - Grant preparation (sample size/power, analysis plans, QA/QC, data management, DSMB)
  - Data management
  - Data Coordinating Center (DCC) activities
  - Analytic Approach
- In the near future we should be able to do similar work with Soarian

Cost

- Partially supported by the CTSA
- Junior investigators and short consults are generally at no cost (CTSA)
- Help with grant applications is generally at no cost
  - Adequate support must be in the grant budget
- Long-term analyses projects require support
  - There are various mechanisms, including P01 program/project grants
- Let's talk

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